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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/402,634 03/27/00 RONI KER

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EXAMINER

HM12/1108

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JAGOE, D

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

11/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/402,634

Applicant(s)

RONIKER ET AL.

Examiner

Donna A. Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I in Paper No. 12 is acknowledged. The traversal is on the ground(s) that these inventions are related as genus (Group I) and partially overlapping sub-genus (Group II), and thus are not unrelated. This is found persuasive and subsequently, the election of species requirement is withdrawn.

Claim Objections

Claims 13 and 24 are objected to because of the following informalities: the word aspirin (asprin) is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-23, 28-31 and 36-39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the limitation "the method of claim 16 wherein the cardiovascular disorder is an inflammation-related disorder". There is insufficient antecedent basis for this limitation in the claim because there is no cardiovascular disorder recited in claim 16. Amending the claim to depend from claim 14 would obviate the rejection.

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Claim 18 recites the limitation "the method of claim 16 wherein the cardiovascular disorder is selected from..." in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no cardiovascular disorder recited in claim 16. Amending the claim to depend from claim 17 (as amended above) would obviate the rejection.

Claims 20-21 recite the limitation "the method of claim 19 wherein the cyclooxygenase-2 inhibitor..." in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claims because there is no cyclooxygenase-2 inhibitor recited in claim 19. Amending the claims to depend from claim 14 would obviate the rejection.

Claim 22 recites the limitation "the method of claim 19 wherein the cyclooxygenase-2 inhibitor is selected..." in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no cyclooxygenase-2 inhibitor recited in claim 19. Amending the claim to depend from claim 21 (as amended above) would obviate the rejection.

Claims 28-29 recite the limitation "the method of claim 27 wherein the cyclooxygenase-2 inhibitor..." in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claims because there is no cyclooxygenase-2 inhibitor recited in claim 27. Amending the claims to depend from claim 25 would obviate the rejection.

Claim 30 recites the limitation "the method of claim 27 wherein the cyclooxygenase-2 inhibitor is selected..." in line 1 of the claim. There is insufficient

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antecedent basis for this limitation in the claim because there is no cyclooxygenase-2 inhibitor recited in claim 27. Amending the claim to depend from claim 29 (as amended above) would obviate the rejection.

Claims 36-37 recite the limitation "the composition of claim 35 wherein the cyclooxygenase-2 inhibitor..." in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claim because there is no cyclooxygenase-2 inhibitor recited in claim 35. Amending the claims to depend from claim 32 would obviate the rejection.

Claim 38 recites the limitation "the composition of claim 35 wherein the cyclooxygenase-2 inhibitor is ..." in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no cyclooxygenase-2 inhibitor recited in claim 35. Amending the claim to depend from claim 37 (as amended above) would obviate the rejection.

The remaining claims are indefinite to the extent that they read on the rejected base claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Searle & Co WO 95/15316.

The claims are drawn to a method for preventing an inflammation-related cardiovascular disorder in a subject comprising treating with a cyclooxygenase-2 (COX-2) inhibitor. Searle & Co. teach the same COX-2 inhibitors for treatment of cardiovascular disorders arising from inflammation (page 7, line 8 to page 8 line 16, see examples and claims 37-56). The treatment vascular diseases of the priority document renders the vascular diseases of the application as anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Searle and Co. WO 95/15316 A in view of the Merck Manual.

The claims are drawn to prophylactic treatment of a subject at risk of developing a cardiovascular disorder comprising treating a subject with a COX-2 inhibitor and *inter alia* a lipid lowering drug such as a statin.

Searle and Co. teach that COX-2 inhibitors would be useful for conditions such as vascular disease and myocardial ischemia and the like (page 7, lines 8-36). The Merck Manual teaches that HMG-CoA reductase inhibitors (statins) can lower LDL levels and prevent unstable angina and MI and decrease the need for surgical coronary

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revascularization. It differs from the instant application in that it does not explicitly teach that these two agents be given together. It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. Motivation for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 6:30 A.M. - 3 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 308-7921 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

dj 
November 5, 2001

ZUNNEN FAV
PRIMARY EXAMINER
GROUP 1200

